

REQUEST FOR PROPOSALS CLINICAL LABORATORY SERVICES

APPENDIX B

RFP STATEMENT OF WORK

TABLE OF CONTENTS

SECTION	TITLE	PAGE
1.0	INTRODUCTION	1
2.0	SCOPE OF WORK	1
3.0	STAFFING AND SPECIFIC TASKS	5
4.0	ADMINISTRATIVE TASKS	7
5.0	SERVICE DELIVERY SITE(S) AND GEOGRAPHIC COVERAGE	7
6.0	QUALITY CONTROL PLAN	8
7.0	CONTRACT DISCREPANCY REPORT	9
8.0	COUNTY OBSERVATIONS	9
9.0	DATA COLLECTION	9
10.0	PRIVACY AND ELECTRONIC SECURITY	9
11.0	SUBCONTRACTOR(S)	10
12.0	GREEN INITIATIVES	10
13.0	PERFORMANCE REQUIREMENTS SUMMARY	10
14.0	OUTCOME MEASUREMENT	11

STATEMENT OF WORK

Clinical Laboratory Services

1.0 INTRODUCTION

1.1 Overview

The Los Angeles County Department of Mental Health (LACDMH) provides mental health services to over 250,000 active clients, many of whom receive prescription medication treatment. Drug therapy and associated care often require supporting clinical laboratory services to ensure patient safety and treatment efficacy. It is the goal of LACDMH to provide both laboratory tests and monitoring in a cost effective and seamless manner by working closely with a comprehensive Laboratory Services Provider (LSP) Contractor to meet the clinical laboratory service needs of LACDMH directly-operated clinics/programs countywide.

1.2 Headings/Acronyms and Terms/Definitions

The headings herein contained are for convenience and reference only and are not intended to define the scope of any provision thereof. Proposer shall refer to, Appendix C, Exhibit 1 for a complete list of acronyms, terms, and definitions.

2.0 SCOPE OF WORK

2.1 Payor Status

LACDMH maintains financial responsibility for clients who have no access to other sources of healthcare benefits. LACDMH clients are always required to pursue enrollment in Medi-Cal, Medicare, or other available coverage sources, but a significant proportion of the LACDMH client population is either ineligible or in a state of transition between coverage periods.

2.1.1 In all cases, LACDMH shall only reimburse Contractor when no other coverage is available for a client. Therefore, LACDMH is the payor of last resort.

2.1.2 Contractor shall maintain contracted status with Medi-Cal, Medicare, or other third parties at all times during the term of the Contract.

2.1.3 Contractor shall be responsible for verifying Medi-Cal, Medicare, and other third-party payor eligibility and for billing Medi-Cal,

Medicare, and third parties directly when a client is eligible. In the event Contractor is unable to bill an eligible client's third party due to loss or nonexistence of a contract, LACDMH reserves the right to decline reimbursement and direct client to an alternate LSP as designated by client's own health plan.

2.2 Laboratory Orders and Results

Contractor is expected to maintain a comprehensive list of available laboratory orders. LACDMH shall provide the "Authorized Order List (AOL)" to Contractor upon execution of the contract.

2.2.1 When an order is received from any LACDMH Provider, and any individual Laboratory Request is not found within the AOL, Contractor shall follow procedures for prior authorization for the individual laboratory request as outlined in the Clinical Laboratory Services Agreement (Appendix A - Sample Contract).

2.2.2 LACDMH shall only reimburse Contractor for orders transmitted electronically or manually on approved forms; verbal orders are **not** permitted. Illegible or unclear orders shall be clarified with ordering facility prior to processing.

2.2.3 LACDMH reserves the right to withhold payment for ambiguous or otherwise non-explicit orders which are processed without authorization or clarification.

2.2.4 Laboratory results shall be transmitted to or made available electronically to LACDMH Providers within a reasonable period of time and in a manner consistent with Health Insurance Portability and Accountability Act (HIPAA) privacy rules. Contractor shall provide approximate response times for laboratory result inquiries.

2.2.5 Each ordering facility within LACDMH shall maintain a separate subaccount with Contractor for the purpose of tracking utilization and transmission of laboratory results. LACDMH Pharmacy Services Bureau is the designated administrative entity on behalf of LACDMH in matters pertaining to the Clinical Laboratory Services Contract, and shall maintain the authority and access to obtain or view laboratory results ordered by any LACDMH Provider upon request.

2.2.6 STAT order results, for orders requested on an immediate basis, are to be returned to LACDMH Provider electronically within four (4) hours of result availability. "Electronically" may occur via uploading to secure internet portal or by fax.

- 2.2.7** Proposers shall review Exhibit 5, Commonly Used Laboratory Test List and provide prices for all laboratory tests listed in Exhibit 5 as well as include the additional fee for each draw/venipuncture procedure as part of the Cost Proposal Format (Referenced in Paragraph 2.10 of the RFP).

2.3 Other Lab Services

- 2.3.1** Proposer is expected to accommodate multiple methods of sample acquisition, including routine or on-call pickup from designated locations, phlebotomy services at point of care, or via staffed blood draw facilities with all of LACDMH's geographic areas.
- 2.3.2** Proposer's sample acquisition programs should be available during directly-operated clinic/program hours of operation or at alternative laboratory service sites that are geographically accessible and located within a convenient proximity of each LACDMH directly-operated ordering facility.
- 2.3.3** Proposer should have policies and procedures in place when a sample is lost or otherwise mishandled by staff or contracted courier.
- 2.3.4** Proposer shall be accessible via telephone, e-mail, or fax during business hours (8:00 a.m. to 5:00 p.m., Monday through Friday) to all LACDMH directly-operated ordering facilities for technical support, laboratory, or other general inquiries.
- 2.3.5** Proposer's laboratory director and personnel shall provide consultation regarding receipt, performance results, and methodological/clinical interpretation of laboratory test results.
- 2.3.6** Proposer shall provide all materials and supplies required to stabilize samples and maintain samples integrity in transit to the laboratory. Such supplies shall be provided to County directly-operated mental health facilities as needed, at no additional cost to the County.
- 2.3.7** Proposer and Proposer's staff shall conform to applicable County facility rules and regulations while conducting clinical laboratory tests on County's premises.

2.4 Requisition Order Forms

- 2.4.1** Contractor shall provide laboratory requisition order forms and catalogs to all LACDMH directly-operated ordering facilities.

LACDMH's proprietary client identification number, known as the "Client IS Number (#)," and other complete patient/client identifying information (e.g., date of birth, Social Security Number, primary insurance) shall be provided on each order form by clinic/program staff authorized to verify Medi-Cal/Medicare eligibility. Client IS # shall be documented by Contractor's information system upon receipt and processing of each requisition order form.

2.4.2 When the Client IS # is not documented or otherwise illegible on a requisition order form, Contractor shall contact directly-operated ordering facility to verify information.

2.4.3 The Client IS # is critical for accurate tracking and analysis of laboratory results in association with departmental quality assurance initiatives.

2.4.4 Client's identifying information, including third-party benefits information, shall be explicitly documented on each requisition order form. Indigent clients shall be documented on requisition order forms as having "No Coverage" by ordering personnel. **Contractor shall contact directly-operated ordering facility for clarification when third-party benefits information is missing or otherwise ambiguous.**

2.5 Invoicing

2.5.1 Payor of Last Resort: Contractor must check client's primary insurance health coverage (e.g., Medi-Cal, Medicare, HMO) to ensure that LACDMH is only submitted invoices for payment when the client has no other third-party payor laboratory benefits coverage. Contractor shall be responsible for verifying Medi-Cal and Medicare eligibility and directly billing Fee-For-Service Medi-Cal and Medicare for services. Verification of Medi-Cal Eligibility Response must accompany the request for payment. Additionally, verification of denial must accompany the request for LACDMH payment before LACDMH reimburses Contractor for denied third-party payor claims. If an erroneous claim is/was submitted, Contractor will reimburse LACDMH for charges.

2.5.2 Contractor shall provide monthly invoices to LACDMH Accounts Payable Division located at 550 S. Vermont Avenue, 8th Floor, Los Angeles, CA 90020 for review. Invoices must include: date of service, client name, LACDMH identifier known as "Client IS #," date of birth, Social Security Number, clinic/program name, name of requesting clinician, laboratory procedure name and catalog

number, itemized charges per ordering facility, client, and monthly cost of all orders to LACDMH.

2.5.3 Bundled laboratory orders consisting of grouped orders must be explicitly itemized. Electronically transmitted invoices must be HIPAA compliant.

2.5.4 LACDMH reserves the right to review orders for accuracy against original requisition order forms. Orders which do not reference original order form shall be held in suspense for payment pending clarification.

2.5.5 County shall pay Contractor for clinical laboratory services in arrears within 30 days of receipt of complete, verified, and correct invoices/billings. Refer to Paragraph 6 (Billing and Payment) in Appendix A, Sample Contract for details.

2.6 Information Systems Integration

LACDMH anticipates implementation of an Electronic Health Record (EHR) in the near future. The goal of LACDMH is to integrate multiple aspects of care, including ordering and viewing of laboratory services and results within one cohesive user interface. Standards based Application Program Interfaces (APIs) for laboratory ordering and viewing of results within external systems should be made available by Contractor when needed for such integration initiatives. Contractor shall have the ability to work cooperatively with LACDMH towards implementation of this interface upon request.

3.0 STAFFING AND SPECIFIC TASKS

Contractor shall furnish all staff, services, supplies, facilities, materials, equipment, vehicles, and other items required to perform the services specified in this RFP and Appendix B, SOW. Additionally, Contractor shall ensure that the following staff and volunteer requirements are met:

3.1 Staffing

3.1.1 On an as needed basis, Contractor shall be called upon to dispatch qualified personnel immediately to draw laboratory test samples from mental health clients treated at directly-operated clinics/programs for laboratory analysis. Contractor shall exercise care and safety precautions when transporting test samples.

3.1.2 Background and Security Investigations and Requirements: Contractor shall ensure that criminal clearances and background checks have been conducted for all Contractor's staff, volunteers,

and all Subcontractor's staff, prior to beginning and continuing work under any resulting contract. The cost of such criminal clearances and background checks is the responsibility of the Contractor whether or not the Contractor or Subcontractor's staff pass or fail the background and criminal clearance investigations.

- 3.1.3 Language Ability:** Contractor's personnel, as well as all Subcontractor's staff who are performing services under this contract, shall be able to read, write, speak, and understand English in order to conduct business with the County. In addition to having competency in English, Contractor shall ensure there is a sufficient number of bilingual staff to meet the language needs of the community served which is to include threshold languages: Chinese, Cambodian, Korean, Russian, Armenian, Spanish, Tagalog, Vietnamese, and Farsi.
- 3.1.4 Service Delivery:** Contractor shall ensure all professional staff, paraprofessional staff, and volunteers providing clinical laboratory services are able to provide services in a manner that effectively responds to differences in cultural beliefs, behaviors and learning, and communication styles within the communities the Contractor provides services.
- 3.1.5 Driver's License:** Contractor shall maintain copies of current drivers' licenses, including current copies of proof of auto insurance of staff providing transportation on an as needed basis to clients.
- 3.1.6 Driving Record:** Contractor shall maintain copies of drivers' State of California Department of Motor Vehicles (DMV) printouts for all Contractor's drivers providing service under this contract. Reports shall be available to LACDMH on request. County reserves the option of doing a DMV check on Contractor's drivers once a year. Contractor shall immediately report to the LACDMH Pharmacy Services Division any accidents and/or loss of equipment, supplies, etc.
- 3.1.7 Experience:** Contractor shall be responsible for securing and maintaining staff who possess expertise and professional licenses and certifications required to provide services required in this SOW. Contractor shall obtain written verification for staff with foreign degrees that the degrees are recognized as meeting established standards and requirements of an accrediting agency authorized by the U.S. Secretary of Education.

3.2 SPECIFIC TASKS

- 3.2.1 Documentation:** Contractor shall maintain documentation in the personnel files of all professional and paraprofessional staff, interns, and volunteers of: (1) all training hours and topics; (2) copies of resumes, degrees, and professional licenses; and (3) current criminal clearances. Contractor shall provide LACDMH, at the beginning of each contract term and within 30 days of any staff change(s), a roster of all staff that includes: (1) names and positions; (2) work schedules; and (3) e-mail addresses, fax and telephone numbers.
- 3.2.2 Changes:** Contractor shall advise LACDMH in writing of any change(s) in Contractor's key personnel at least 24-hours before proposed change(s), including names and qualifications of new personnel. Contractor shall ensure that no interruption of services occurs as a result of the change in personnel.
- 3.2.3 Customer Satisfaction Survey and Client Status Report:** Contractor is required to submit information quarterly from clients regarding their clinical progress and satisfaction with clinical laboratory services to the LACDMH Pharmacy Services Division located at: 550 S. Vermont Avenue, 9th Floor, Los Angeles, CA 90020.

4.0 ADMINISTRATIVE TASKS

- 4.1 Days/Hours of Operation:** Proposer shall provide the name, e-mail address, and telephone number of the contact person for after-hours services. Proposer's service delivery sites shall be open at a minimum from Monday through Friday, from 8:00 a.m. until 5:00 p.m. In addition, Proposer's Project Manager or County approved alternate shall have full authority to act for Proposer on all matters relating to the daily operation of this contract and shall be available during the County's regular business hours of Monday through Friday, from 8:00 a.m. until 5:00 p.m., to respond to County inquiries and to discuss problem areas.

5.0 SERVICE DELIVERY SITE(S) AND GEOGRAPHIC COVERAGE

- 5.1** Proposer must be in compliance with all federal, State, and local laws and regulations pertaining to certification rules as identified in the contract between the Los Angeles County Mental Health Plan and the State of Department of Mental Health, referred to as State or SDMH.
- 5.2** Services shall be delivered at the service delivery sites listed by Proposer. Proposer shall request approval from the LACDMH Program Manager in

writing a minimum of 30 days before terminating services at any of the location(s) listed before commencing services at any other location(s) not previously approved in writing by the LACDMH Program Manager. *All service delivery sites listed by Proposer must be operational within 30 days of the commencement of the contract.*

- 5.3 All changes must be made in accordance with Amendments to the contract, Paragraph 38, Alteration of Terms (Appendix A - Sample Contract).
- 5.4 Proposer shall have the capability to provide clinical laboratory services for all LACDMH directly-operated mental health clinics/programs located within Los Angeles County's geographic boundaries. Proposer **must** provide clinical laboratory services, e.g., collecting samples for specific tests, performing tests, for clients in directly-operated mental health clinics/programs at a time scheduled by the clinics/programs and at laboratory service sites which are geographically accessible. The purpose of these laboratory service sites is to provide mental health clients with the alternative of going to a laboratory service site without an appointment. **Clinical managers are to have a say as to when and where blood draws are to be done.**

6.0 QUALITY CONTROL PLAN

- 6.1 Proposer shall establish and utilize a comprehensive Quality Control Plan to assure that County procedures are in place for identifying and correcting clinical laboratory testing deficiencies; handling complaints and incident reports; and ensuring compliance with all requirements, County audits, and professional and legal standards. The Plan must be submitted to LACDMH for review and approval. The Plan shall be effective on the contract start date and shall be updated and resubmitted for LACDMH approval as changes occur. The Plan shall include:
 - 6.1.1 Activities to be monitored, frequency of monitoring, samples of forms to be used in monitoring, title/level and qualifications of personnel performing monitoring functions.
 - 6.1.2 Ensuring the services, deliverables, and requirements defined in the contract are being provided at or above the level of quality agreed upon by the County and the Proposer.
 - 6.1.3 Ensuring that professional staff rendering services under the contract have the necessary prerequisites.
 - 6.1.4 Identifying and preventing deficiencies in the quality of service before the level of performance becomes unacceptable.

- 6.1.5** Taking any corrective action, if needed, including a commitment to provide to the County upon request a record of all inspections, the corrective action taken, the time the problem is first identified, a clear description of the problem, and the time elapsed between identification and completed corrective action.
- 6.1.6** Continuing to provide services to the County in the event of a strike or other labor action of the Proposer's employees.
- 6.1.7** A record of all inspections conducted by the Proposer, any corrective action taken, the time a problem was first identified, a clear description of the problem, and the time elapsed between identification and completed corrective action, shall be provided to the County upon request.

7.0 CONTRACT DISCREPANCY REPORT (Appendix C, Exhibit 3)

Verbal notification of a contract discrepancy will be made to the Contract Project Monitor as soon as possible whenever a contract discrepancy is identified. The problem shall be resolved within a time period mutually agreed upon by the County and the Contractor. The County Contract Project Monitor will determine whether a formal Contract Discrepancy Report (CDR) shall be issued. Upon receipt of this document, the Contractor is required to respond in writing to the County Contract Project Monitor within five (5) business days, acknowledging the reported discrepancies or presenting contrary evidence. A plan for correction of all deficiencies identified in the CDR shall be submitted to the County Contract Program Manager within ten (10) business days.

8.0 COUNTY OBSERVATIONS

In addition to departmental contracting staff, other County personnel may observe performance, activities, and review documents relevant to this contract at any time during normal business hours. However, these personnel may not unreasonably interfere with the Contractor's performance.

9.0 DATA COLLECTION

Contractor shall have the ability to collect, manage, and submit data as directed by LACDMH to demonstrate client outcomes inclusive of the guidelines set forth by LACDMH and the State. Contractor shall perform data entry to support these activities.

10.0 PRIVACY AND ELECTRONIC SECURITY

- 10.1** Proposer shall comply with federal and State laws as they apply to Protected Health Information Individually Identifiable Health Information, and electronic information security.
- 10.2** Any Proposer that is deemed a "Covered Entity" HIPAA shall comply with the HIPAA privacy and security regulations independently of any activities or support of LACDMH or the County of Los Angeles.
- 10.3** Any Proposer that is deemed a "Business Associate" of County under HIPAA shall enter into a Business Associate Agreement with the County of Los Angeles to ensure compliance with the privacy and electronic security standards.

11.0 SUBCONTRACTOR(S)

- 11.1** If Proposer intends to employ a Subcontractor(s) to perform some of the services described in this SOW, the transmittal letter shall clearly indicate the other agency(s) involved, and Proposer shall clearly describe the role of the Subcontractor in the provision of clinical laboratory services in the Proposal Package. A statement from all Subcontractors indicating their willingness to work with the Proposer and the intent to sign a formal contract between the parties shall be submitted with the signature of the person authorized to bind the subcontracting organization.
- 11.2** If Proposer is selected for funding, Proposer shall obtain prior written approval from LACDMH in order to enter into a particular subcontract and all requests must be in writing. Proposer shall remain responsible for any and all performance required of it under the contract.
- 11.3** All Subcontracting Agreements shall be required for County review after award of the contract, if any.

12.0 GREEN INITIATIVES

- 12.1** Contractor shall use reasonable efforts to implement "green" practices for environmental and energy conservation benefits.
- 12.2** Contractor shall notify County's Program Manager of Contractor's new green initiatives prior to the contract commencement.

13.0 PERFORMANCE REQUIREMENTS SUMMARY

- 13.1** A Performance Requirements Summary (PRS) chart, Appendix C, Exhibit 4 listing required services that will be monitored by the County during the term of this contract is an important monitoring tool for the County.
- 13.2** All listings of services used in the PRS are intended to be completely consistent with the contract and the SOW, and are not meant in any case to create, extend, revise, or expand any obligation of Contractor beyond that defined in the contract and the SOW. In any case of apparent inconsistency between services as stated in the contract and the SOW and the PRS, the meaning apparent in the contract and the SOW will prevail. If any service seems to be created in the PRS which is not clearly and forthrightly set forth in the contract and the SOW, that apparent service will be null and void and place no requirement on Contractor.

14.0 OUTCOME MEASUREMENT

- 14.1** Contractor's ability to perform as required will be measured via the following methods:
 - 14.1.1** Ongoing tracking of Contractor or client complaints pertaining to level of service provided by Contractor.
 - 14.1.2** Ongoing monitoring and documentation of Contractor's billing inaccuracies by LACDMH Accounts Payable Division.
 - 14.1.3** Ongoing tracking of unauthorized laboratory orders processed by Contractor.